

JAN 23 2001

**Section 510(k) Premarket Notification Summary
(as required by 807.92 (j))**

K003639

Submitter: Vital Images, Inc.
3300 Fernbrook Lane North -Suite 200
Plymouth, MN 55447-5341
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Date Prepared: November 22, 2000

Contact Person: Robert C. Samec

Device Trade Name: CT Perfusion Option for Vitrea 2

Device Common Name: Image Processing Software for CT Scanners

Classification Name: 90JAK - CT, Image Processing

Substantially Equivalent To:

CT Perfusion (K993791)	Perfusion CT (K982636)	AW Functool Option (K960265)
GE Medical Systems	Siemens Medical Systems	GE Medical Systems
P.O.Box 419	186 Wood Avenue South	P.O. Box 419
Milwaukee, WI 53201	Iselin, NJ 08830	Milwaukee, WI 53201

Indications for Use: For post processing imaging based on dynamic CT images continuously acquired during the injection of contrast for the visualization of apparent blood flow in brain tissue and pictorial illustration of perfusion related parameters to aid in the assessment of the type and extent of cerebral perfusion deficiencies.

Device Description:: Perfusion CT is a post processing software package (option), which runs on a NT, based platform (Vitrea 2) designed to post process CT images. The CT Perfusion Option supports the evaluation of dynamic CT data gathered during the injection of a compact bolus of contrast media, where the contrast media acts as a pure intravascular tracer. Perfusion CT calculates parameters related to brain perfusion: cerebral blood flow (CBF), cerebral blood volume (CBV) and local bolus timing (MTT) from one set of dynamic images.

Software Development: The software utilized was designed, developed, tested and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation and maintenance.

Performance Testing: The CT Perfusion Option will successfully complete Integration testing/verification prior to beta validation.

Clinical Evaluation: Software Beta testing will be successfully completed validating the CT Perfusion Option prior to market release.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2001

Robert C. Samec
Vice President QA/RA
Vital Images, Inc.
3300 Fernbrook Lane North, Suite 200
PLYMOUTH MN 55447-5341

Re: K003639
CT Perfusion Option for Vitrea 2
Dated: November 22, 2000
Received: November 24, 2000
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Samec:

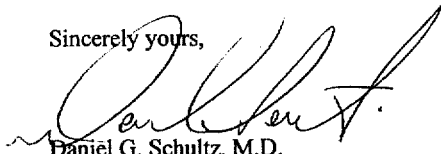
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K 00 3639

Device Name: CT Perfusion Option for Vitrea 2

INDICATIONS FOR USE:

Intended Use:

Indications for Use: For post processing imaging based on dynamic CT images continuously acquired during the injection of contrast for the visualization of apparent bloodflow in brain tissue and pictorial illustration of perfusion related parameters to aid in the assessment of the type and extent of cerebral perfusion disturbances.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

~~Concurrence of CDRH, Office of Device Evaluation (ODE)~~

Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The-Counter Use) _____

(Optional Format 1-2-96)

David A. Ferguson
(Division Sign-Off)
Division of Reproductive and Radiological Devices
510(k) Number K003639